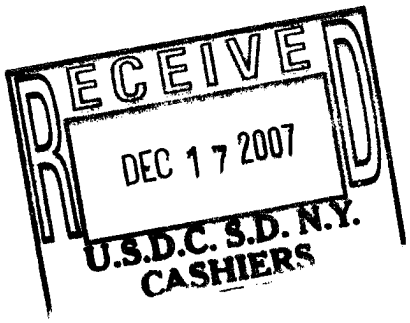

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

JUDITH M. LAYZER and
RAY J. FISCHER,

Plaintiffs,

v.

MICHAEL O. LEAVITT, in his official capacity as SECRETARY OF THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Defendant.

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07 CV 11339

No. 07-CV-_____ (___)

COMPLAINT

Plaintiffs Judith M. Layzer and Ray J. Fischer, by their undersigned attorneys, for their Complaint in this action allege as follows:

INTRODUCTION

The Medicare prescription-drug benefit established in January 2006 was meant to give older adults and people with disabilities better health care and greater financial security. For years, many people with Medicare—increasingly reliant on prescription drugs—tried to cobble together coverage for their medications through an unwieldy and often inadequate combination of programs. Often people with Medicare had been left with the choice of paying for their prescription medicines at the expense of other basic needs.

Yet the new Medicare prescription-drug benefit (Part D), enacted in the Medicare Prescription Drug Improvement and Modernization Act of 2003 ("MMA"), has

left many people who enrolled in it without coverage for prescriptions they need. Indeed, many people with Part D were actually better off before it was introduced.

Among those in this situation are people, such as Plaintiffs Judith M. Layzer and Ray J. Fischer, whose doctors have prescribed medically necessary medications for "off-label" uses. "Off-label" uses exist because drugmakers seek Food and Drug Administration ("FDA") approval for specific uses of their products, and drugmakers conduct trials to test their drugs' safety and effectiveness in patients with specific conditions. If the FDA approves a drug, then the drugmaker must sell the drug with a label that lists only its FDA-approved uses. Any other use is referred to as "off-label." Off-label uses are very common: In 2001, over 20 percent of prescriptions written for the 500 most commonly used drugs were for off-label uses.

Regulations issued last year by the Defendant, Health and Human Services Secretary Michael O. Leavitt, would bar Part D coverage of off-label prescriptions, unless the prescribed use is supported in one of three medical compendia that summarize drug uses that are mentioned in certain clinical studies and peer-reviewed medical literature. If a drug's prescribed use is not listed in the compendia, however, then a Part D plan cannot cover the drug—even if research published in peer-reviewed medical journals shows that the drug is effective for the prescribed use, and even if the drug is medically necessary for the patient.

People who take off-label prescriptions often do so after trying treatment after treatment to no avail, sometimes experiencing debilitating side effects for years. They, along with their doctors, are thrilled to finally find medications that ease their

discomfort or, in some cases, preserve their lives. Yet such people then discover that even though the drugs are on their Medicare Part D plans' formularies, the drugs cannot be covered for them. Without coverage of off-label prescriptions, people face increased suffering. And Medicare often bears increased costs, because of the need for more drastic care, such as emergency hospitalizations, that results when people do not receive the medicines that they need.

The exclusion from Medicare Part D coverage of off-label uses that are not mentioned in the compendia hurts the most vulnerable people with Medicare. The exclusion of these off-label prescriptions also conflicts with standard medical practice.

This action is brought on behalf of Mrs. Layzer and Mr. Fischer to enjoin the Secretary of Health and Human Services from denying coverage of prescriptions that are medically necessary to Plaintiffs' fights against ovarian cancer and muscular dystrophy, respectively. This action also seeks a declaration that the Secretary's interpretation of the Medicare statute, to bar coverage of certain medically necessary off-label medications that otherwise are covered by Part D, is unlawful.

NATURE OF THE ACTION

1. Plaintiff Judith M. Layzer, a 67-year-old widow, is a survivor of ovarian cancer. Since 1999, Mrs. Layzer has taken a medication called Cetrotide, which her doctors have prescribed to treat and limit her cancer. Until January 2006, Mrs. Layzer's out-of-pocket monthly co-payment for her Cetrotide never exceeded $40.

2. On January 1, 2006, the federal government launched its Medicare prescription-drug program, known as Medicare Part D ("Part D"). Once enrolled in

Part D, Mrs. Layzer was denied coverage of her Cetrotide prescription. As a result of this denial, Mrs. Layzer has paid co-payments of *over $7,000 per month* for her prescription.

3. Cetrotide is essential to maintaining Mrs. Layzer's health and preserving her life. Mrs. Layzer's doctors have repeatedly stated that Cetrotide is medically necessary to treat her ovarian cancer. Her doctors' conclusion has strong support in peer-reviewed medical literature.

4. Because Cetrotide is medically necessary to Mrs. Layzer's health, the denial of Medicare Part D coverage of her prescription is dangerous and unlawful.

5. In the initial stages of coverage determination, the denial was based on the misconception that Mrs. Layzer used Cetrotide as a fertility drug. Mrs. Layzer has had both ovaries removed. She does not use Cetrotide as a fertility drug.

6. Later, Mrs. Layzer was denied coverage on the ground that Cetrotide can never be a "covered Part D drug" when used to treat ovarian cancer, even though—according to Defendant and his agents—Cetrotide is a "covered Part D drug" for other purposes, including treating prostate cancer.

7. As for Plaintiff Ray J. Fischer, he is a Medicare beneficiary by reason of disability. He has been diagnosed with myotonic muscular dystrophy type 2 ("DM2"), a rare, degenerative form of muscular dystrophy that results in muscle weakness, tremors, and cerebral, endocrine, and cardiac abnormalities.

8. After many years of ineffective treatments, Mr. Fischer's physician prescribed Increlex. Increlex costs Mr. Fischer over $75,000 per year out of

pocket. Mr. Fischer has paid this exorbitant sum because Increlex has significantly improved his health.

9. When the drug benefit became available under Medicare Part D, Mr. Fischer researched many Part D prescription drug plans. Relying on a conversation he had with a representative of the Cignature Rx Value Plan ("Cigna"), who informed him that this plan would cover Increlex, Mr. Fischer joined the Cigna Part D plan. Cigna then proceeded to deny coverage for Mr. Fischer's Increlex prescription.

10. After redetermination requests and administrative appeals, Mr. Fischer is still being denied coverage of his Increlex prescription.

11. Because Increlex is medically necessary to Mr. Fischer's health, the denial of Medicare Part D coverage of his prescription is dangerous and unlawful.

12. The Secretary's determinations that Cetrotide is not a "covered Part D drug" when used to treat ovarian cancer, and that Increlex is not a "covered Part D drug" when used to treat mytonic muscular dystrophy, stem from a misreading of the Medicare Part D statute.

13. Mrs. Layzer and Mr. Fischer bring this action to compel the Secretary of the United States Department of Health and Human Services ("HHS") to fulfill his statutory duty to ensure that Plaintiffs receive Part D coverage of life-saving prescription drugs. Mrs. Layzer and Mr. Fischer also seek a declaration that Defendant's interpretation of the statute at issue, 42 U.S.C. § 1395w–102(e), is unlawful.

JURISDICTION AND VENUE

14. This Court has jurisdiction of this action pursuant to 42 U.S.C. § 1395w-104(h), which incorporates 42 U.S.C. § 405(g). Under these provisions, the amounts in controversy here—over $100,000 for Mrs. Layzer and over $75,000 for Mr. Fischer—far exceed the 2007 threshold of $1,130 for judicial review of Medicare-benefits decisions. *Medicare Appeals: Adjustment to the Amount in Controversy Threshold Amounts for Calendar Year 2007*, 71 Fed. Reg. 75,250 (Dec. 7, 2006).

15. This Court also has jurisdiction of this action under 28 U.S.C. § 1361, which permits this Court to hear Plaintiffs' claims that they are entitled to mandamus relief because the Secretary has violated a non-discretionary mandate.

16. Venue in this district is proper pursuant to 28 U.S.C. § 1391(e). A substantial part of the events or omissions giving rise to the claims occurred within the Southern District of New York. Mrs. Layzer and Mr. Fischer both reside within the Southern District of New York.

THE PARTIES

17. Plaintiff Judith M. Layzer is a 67-year-old widow. She resides in the County of New York, New York.

18. Plaintiff Ray J. Fischer is 64 years old. He resides in the County of Westchester, New York.

19. Defendant Michael O. Leavitt (the "Secretary") is sued in his official capacity as the Secretary of the United States Department of Health and Human Services ("HHS"). The Secretary has responsibility for the policies and conduct of HHS.

THE FACTS

Judith M. Layzer, Her Ovarian Cancer, and Her Cetrotide Prescription

20. Judith M. Layzer, a 67-year-old Medicare beneficiary, has had a rare form of ovarian cancer called Granulosa Cell Tumor ("GCT") since 1971. For the past 20 years, Mrs. Layzer has been treated with surgery, radiation, and medication.

21. In 1999, after one of Mrs. Layzer's tumors ruptured, several gynecological oncologists advised her to take Cetrotide to control her cancer. Mrs. Layzer has been prescribed Cetrotide since 1999.

22. The Food and Drug Administration ("FDA") has approved Cetrotide as a safe and effective medication.

23. Cetrotide has reduced the hemorrhaging that had plagued Mrs. Layzer, and it has stabilized her tumor growth. That is why Robert Bast, M.D., Mrs. Layzer's oncologist at the University of Texas M.D. Anderson Cancer Center, has prescribed Cetrotide for Mrs. Layzer for the past several years.

24. Dr. Bast's determination regarding Cetrotide's medical necessity to Mrs. Layzer has been confirmed by many other doctors, including Dr. Rogerio A. Lobo, former Chairman of the Obstetrics and Gynecology Department at the Columbia University Medical Center; Dr. J. Gregory Mears, a senior medical oncologist at the Columbia University Medical Center; Dr. Andrzej Kudelka, a senior medical oncologist at the Stony Brook Medical Center; Dr. Jimmie Holland, a psychiatric oncologist at the Memorial Sloan-Kettering Cancer Center; and Dr. Peter E. Schwartz, Assistant Chief of the Obstetrics and Gynecology Department at the Yale–New Haven Hospital.

The Denial of Part D Coverage of Mrs. Layzer's Prescription

25. Prior to the implementation of Medicare Part D, Mrs. Layzer's prescription for Cetrotide was covered by her New York City government retiree insurance, administered by Group Health Incorporated ("GHI"). With this coverage, Mrs. Layzer's out-of-pocket co-payment for Cetrotide never exceeded $40 per month.

26. On July 1, 2005, Mrs. Layzer became eligible for Medicare, the federal program that provides comprehensive health-insurance coverage at affordable cost to older adults or to persons who have disabilities. Medicare was established by Congress in 1965 to ensure continuity of care, allowing full choice of doctors and hospitals, for groups of people whom private insurers had considered to be "bad risks."

27. With the Medicare drug benefit, however, the only way that people with Medicare, including Mrs. Layzer, can receive the drug benefit is by buying coverage from a private insurance plan.

28. In January 2006, after the implementation of the MMA, Mrs. Layzer's prescription-drug coverage was modified. Mrs. Layzer's former employer, the City of New York, moved its retiree members to the City of New York Enhanced Medicare Part D Program, a plan also administered by GHI. Almost immediately, in Mrs. Layzer's first six weeks of being on this plan, GHI denied Part D coverage of Mrs. Layzer's Cetrotide prescription.

29. Mrs. Layzer requested a Redetermination of this decision, in accordance with statutory Part D administrative-appeal procedures. On February 10, 2006, GHI issued a Redetermination Notice affirming its denial of Medicare Part D

coverage, stating the drug was "not covered under Medicare Part D." Mrs. Layzer appealed once more. On February 24, 2006, GHI again denied coverage, and again stated that Cetrotide is not covered under the Medicare Part D benefit.

30. In February 2006, GHI announced that it would cover Mrs. Layzer's Cetrotide for one year (which was later extended another year) under the "enhanced" portion of her plan. But GHI imposed a massive co-payment. From April 2006 to June 2007, Mrs. Layzer paid a co-payment of at least $7,208 each month.

31. On April 5, 2006, Mrs. Layzer appealed GHI's denial of coverage to the Independent Review Entity ("IRE"), Maximus Federal Services ("Maximus").

32. On April 17, 2006, Maximus issued an unfavorable decision, claiming that GHI "is not required to provide coverage for Cetrotide because it is not being used for a medically accepted indication." The Maximus decision stated that "a medically accepted indication means a use that is approved by the FDA or a use that is supported by one or more citations in the [ ] drug compendia." The Maximus physician reviewer stated that "while a literature search verified that Cetrotide has anticancer activity in *in vitro* and *in vivo* ovarian cancer models, I can find no evidenced [sic] based medical literature supporting the use of this drug for her clinical condition."

33. In fact, there has been at least one study of Cetrotide in humans as a treatment for ovarian cancer, and it has been hailed as producing "results [that] are quite remarkable." Other medical research has shown that Cetrotide is effective against ovarian-cancer cell lines.

ALJ Smith's Decision Denying Coverage: The Denial Is "Frustrating," Is "Contrary," and "Makes No Sense"

34. Mrs. Layzer then appealed the denial of coverage to The Honorable Gary D. Smith ("Judge Smith"), a United States Administrative Law Judge ("ALJ") with the Office of Medicare Hearings and Appeals.

35. Judge Smith determined, as a factual finding, that "the medical necessity of Cetrotide to treat the Appellant's ovarian cancer . . . has been firmly established by three prominent and highly qualified physicians who are familiar with the Appellant and with her uniquely serious medical condition." Judge Smith found that "[t]he evidence clearly establishes that the use of Cetrotide to treat [Mrs. Layzer's] ovarian cancer is reasonable and necessary."

36. Judge Smith also found that peer-reviewed medical literature recognizes and supports the use of Cetrotide to treat ovarian cancer.

37. Judge Smith also determined that no other drug on the GHI formulary is as effective as Cetrotide in treating Mrs. Layzer's cancer.

38. Still, Judge Smith ruled that Cetrotide was not covered by Part D. Judge Smith wrote that his own ruling was "frustrating" and that it "makes no sense."

39. In particular, Judge Smith noted that his ruling created a discrepancy in Medicare's coverage of Mrs. Layzer's Cetrotide prescription: Part D would not cover it, but Part B—the part of Medicare that covers outpatient care and certain medications administered by doctors—would. As Judge Smith noted, "It seems contrary to allow Medicare Part B coverage of an 'off-label' use that is supported by peer reviewed literature, yet not allow Medicare Part D coverage" of the very same use.

The MAC's Affirmance of the Denial of Coverage: The MAC Lacks Authority To Consider Mrs. Layzer's Argument from the Statute

40. Mrs. Layzer appealed Judge Smith's decision to the Medicare Appeals Council ("MAC") on April 23, 2007.

41. On November 30, 2007—fully 221 days later, in violation of the requirement that the MAC must decide appeals within 90 days—Mrs. Layzer received a decision on her appeal.

42. In its decision, the MAC noted that "Cetrotide is a prescription drug approved by the Food and Drug Administration."

43. The MAC also conceded that "There is no dispute that [Mrs. Layzer] and her physicians consider the medication at issue as a life-sustaining treatment" in Mrs. Layzer's fight against cancer.

44. In its decision, the MAC also acknowledged that according to record evidence, Cetrotide is indeed medically necessary to Mrs. Layzer's health:

> The Council acknowledges, as did the ALJ, that the enrollee has presented the opinions of three physicians familiar with her medical condition who have concluded that Cetrotide is essential for the treatment of her cancer, and that no other drug on the plan's formulary is as effective for her medical condition. The enrollee has also submitted peer-reviewed literature that, the ALJ concluded, "recognizes and supports the use of Cetrotide to treat ovarian cancer."

45. Despite this evidence that Cetrotide is a medically necessary "life-sustaining treatment" for Mrs. Layzer, the MAC upheld the denial of Part D coverage of her Cetrotide prescription.

46. In denying coverage of this life-sustaining treatment, the MAC held that if Cetrotide is used to treat ovarian cancer, it "does not meet the definition of a Part D drug, as defined in 42 C.F.R. § 423.100."

47. The MAC also stated that "neither the ALJ nor the Council has the authority to reverse [the denial of coverage] based on the assertion that the Medicare Part D regulation's definition of a Part D drug, as provided in 42 C.F.R. § 423.100 . . . [is] inconsistent with the statute."

Ray Fischer, His Muscular Dystrophy, and His Increlex Prescription

48. Ray Fischer is 64 years old. He is a Medicare beneficiary by reason of disability. He has been diagnosed with myotonic muscular dystrophy type 2 ("DM2"), a rare, degenerative form of muscular dystrophy that results in muscle weakness, tremors, and cerebral, endocrine, and cardiac abnormalities.

49. Mr. Fischer's DM2 has progressed over the years. It began with tremors that he experienced in late childhood. The tremors evolved into muscle weakness and lack of motor control.

50. For decades, Mr. Fischer's tremors, muscle weakness, and lack of motor control did not respond to physical therapy or medication. Mr. Fischer tried various treatments in an attempt to halt the progression of the disease. He tried testosterone shots for the muscle deterioration, atenolol for the tremor, and naproxen for pain. He underwent years of intermittent physical therapy in order to improve his ability to walk. These treatments, however, did not result in significant benefits for Mr. Fischer.

51. Indeed, over the last 10 to 15 years, the rate of Mr. Fischer's muscular deterioration increased. Mr. Fischer developed substantial weakness in his quadriceps, which caused his legs to buckle and made it difficult for him to climb stairs or to stand up from a chair. Over the years, Mr. Fischer lost the ability to shave both sides of his face, to balance while standing upright, and to put on a jacket without assistance. Now, Mr. Fischer can no longer walk. He began using a walker in 2003, but due to deterioration in leg strength, he has been wheelchair-bound since 2004. DM2 caused Mr. Fischer's tremors to progress significantly, preventing him from completing simple tasks such as bringing a spoon to his mouth or holding a glass.

The Medical Necessity of Increlex

52. In 2005, Mr. Fischer and Dr. Richard Moxley, director of the Neuromuscular Disease Center at the Rochester Medical Center, identified a promising 1995 study of using insulin-like growth factor-1, marketed under the brand name Increlex, to treat patients with myotonic muscular dystrophy type 1 ("DM1"). After treatment with Increlex for 16 weeks, study participants had exhibited significant increases in muscle strength, in insulin response, and in protein synthesis. The study looked at patients with DM1, but after considering the similarities between DM1 and DM2, Dr. Moxley thought that Mr. Fischer might benefit from Increlex. Dr. Moxley therefore prescribed Increlex for Mr. Fischer.

53. On March 24, 2006, Mr. Fischer began Increlex injections. Within weeks, Mr. Fischer began to notice improvements in his symptoms. The deterioration of his muscles slowed or stopped, and his muscle strength and range of motion improved.

His hand-arm tremor has "all but disappeared." As a result of these improvements, Mr. Fischer now can put on a jacket without help, shave both sides of his face, drive, transfer himself out of his wheelchair independently, and eat hot soup from a spoon without fear of burning himself.

54. This improvement is verified by Mr. Fischer's scores on the Neuromuscular Function Scale ("NFS"), which measures muscle strength based on a set of 28 activities. When Mr. Fischer began taking Increlex, his NFS scores were in the range of 63 to 69. Since then, however, his NFS scores have risen to 84 in January 2007, and later in 2007 to 89.

55. Dr. Moxley confirms that Mr. Fischer has received important benefits from Increlex:

> [Mr. Fischer] is able to maneuver better in his wheelchair and the range of motion in his arms is improved. He is less troubled by his hand-arm tremor. These benefits have helped to optimize his quality of life and maintain his present level of independence. The most important benefit that Mr. Fischer has experienced is that there has been no major worsening of his weakness.

56. As Dr. Moxley and Mr. Fischer both attest, Increlex has halted the progression of Mr. Fischer's disease. Without Increlex, however, Mr. Fischer's debilitating disease can be expected to progress as it did before, and his health will be gravely threatened.

Mr. Fischer's Struggle with Cignature Rx Value Plan and Denial of Part D Coverage

57. Because Mr. Fischer's condition is complex and rare—it is considered an orphan disease—he took care in choosing his Part D plan. Before enrolling in a plan, Mr. Fischer carefully reviewed the many options available to him, hoping to find a plan that would cover Increlex.

58. Mr. Fischer has testified that before enrolling in the Cigna plan, he spoke to a Cigna representative who confirmed that Increlex was on the plan's formulary and would be covered, as long as his physician submitted a prior-authorization request. On February 27, 2007, Dr. Moxley did submit a request for prior authorization for Increlex, but Cigna then denied coverage.

59. Mr. Fischer requested a redetermination, emphasizing that Increlex is medically necessary for him. Cigna nevertheless affirmed its denial of coverage.

60. On June 16, 2007, Mr. Fischer filed an expedited appeal with Maximus Federal Services. On June 18, 2007, Maximus issued an unfavorable decision.

61. Maximus claimed that although Dr. Moxley had cited a peer-reviewed study that demonstrated encouraging results for Increlex used to treat myotonic muscular dystrophy, "medically accepted indications do not include uses in research or uses described in peer reviewed medical literature."

ALJ Sterner's Decision Denying Coverage:
"An ALJ May Not Promulgate Law"

62. Mr. Fischer appealed the denial of coverage to The Honorable Steven L. Sterner ("Judge Sterner"), an ALJ with the Office of Medicare Hearings and Appeals.

63. In his Decision, issued on September 5, 2007, Judge Sterner found that Increlex is a prescription drug approved by the FDA and that it appears on Cigna's formulary. Judge Sterner noted that "[Appellant] testified that the Plan's formulary did not include any other medications which would be appropriate for his condition."

64. Judge Sterner agreed that "a study has been completed that establishes the efficacy of Increlex in treating the Appellant's condition."

65. Judge Sterner also noted, "Since taking Increlex, Appellant can now pick up a cup of coffee and lift it to his lips. He has regained the strength and control of his quadriceps muscles . . . and the tremor in his hand had all but abated."

66. Judge Sterner concluded, "Appellant's situation is a compelling one. After listening to the testimony, there is no doubt that his physical limitations have had a significant negative impact upon his life."

67. Nevertheless, Judge Sterner upheld Cigna's denial of coverage of Increlex. This decision was based on a reading of the Secretary's regulatory definition of the term "covered part D drug." 42 C.F.R. § 423.100. Judge Sterner reasoned that he was bound by the limiting definition in the regulations, because "an ALJ may not promulgate law."

The MAC's Affirmance of the Denial of Coverage:
The MAC Lacks Authority To Consider
Mr. Fischer's Argument from the Statute

68. Mr. Fischer appealed Judge Sterner's decision to the MAC on November 1, 2007. On December 3, 2007, Mr. Fischer received a decision on his appeal.

69. In its decision, the MAC admitted that "[t]here is no dispute that appellant and his physician consider the medication at issue to be medically necessary."

70. Despite conceding that Increlex is medically necessary for Mr. Fischer, the MAC upheld the denial of Part D coverage of his Increlex prescription.

71. In denying coverage of this medically necessary drug, the MAC held that Increlex, as used to treat DM2, "does not meet the definition of a Part D drug, as defined in 42 C.F.R. § 423.100."

72. The MAC also stated that "both ALJs and the Council are required to follow the Department's regulations."

COUNT ONE
(Medicare Prescription Drug Improvement and Modernization Act,
42 U.S.C. § 1395w-101 *et seq.*)
The Secretary Has Failed To Ensure Prescription-Drug
Coverage for a Beneficiary Statutorily Entitled to Such Coverage

73. Mrs. Layzer and Mr. Fischer incorporate by reference the allegations of paragraphs 1 through 72 of this Complaint as if fully set forth herein.

74. Under the MMA, as of January 1, 2006, every eligible person is entitled to prescription-drug coverage under a Part D plan. The Secretary has the statutory duty to ensure that each eligible participant in Part D receives access to "covered Part D drugs."

75. The Secretary has failed to ensure that Mrs. Layzer and Mr. Fischer, who are both eligible and enrolled Part D participants, receive coverage for "covered Part D drugs."

76. As a result, Mrs. Layzer and Mr. Fischer have been denied their statutory rights to prescription-drug coverage under Medicare Part D.

77. Mrs. Layzer and Mr. Fischer have also sustained out-of-pocket expenses for which they are entitled to reimbursement.

COUNT TWO
(Administrative Procedure Act, 5 U.S.C. § 706(1))
The Secretary Has Unlawfully Failed To Prevent the
Denial of Coverage of a Medically Required Covered Part D Drug

78. Mrs. Layzer and Mr. Fischer incorporate by reference the allegations of paragraphs 1 through 77 of this Complaint as if fully set forth herein.

79. Under the MMA, the Secretary has a statutory duty to provide access to all "covered Part D drugs."

80. In the cases of Mrs. Layzer and Mr. Fischer, the Secretary has unreasonably withheld statutorily required determinations and has unlawfully failed to take required actions.

81. The Secretary's failures to make legally required determinations, and to take required actions, have damaged Mrs. Layzer and Mr. Fischer.

82. As a result of the Secretary's failures, Mrs. Layzer and Mr. Fischer have been denied their statutory rights to Medicare Part D coverage of their prescriptions.

COUNT THREE
(Administrative Procedure Act ("APA"), 5 U.S.C. § 706(2))
The Secretary's Actions Are Arbitrary and
Capricious in Violation of the APA and the SSA

83. Mrs. Layzer and Mr. Fischer incorporate by reference the allegations of paragraphs 1 through 82 of this Complaint as if fully set forth herein.

84. The action of the Secretary in denying Part D coverage of Plaintiffs' prescriptions are unlawful and should be set aside for depriving Medicare beneficiaries of statutory rights as provided by the Social Security Act ("SSA").

85. The Secretary's findings that Cetrotide and Increlex, as used by Mrs. Layzer and Mr. Fischer, are not covered Part D drugs should be set aside as unlawful, short of statutory right, unwarranted by the facts, and arbitrary and capricious.

PRAYER FOR RELIEF

WHEREFORE, Mrs. Layzer and Mr. Fischer respectfully request that this Court enter judgment:

a. Declaring that a prescription drug need not be prescribed for a "medically accepted indication," as defined by 42 U.S.C. § 1396r-8(k)(6), to be a "covered Part D drug," as defined by 42 U.S.C. § 1395w-102(e);

b. Declaring that Cetrotide as used by Mrs. Lazyer to treat ovarian cancer, and Increlex as used by Mr. Fischer to treat DM2, are "covered Part D drugs";

c. Enjoining the Secretary from denying Part D coverage of Mrs. Layzer's Cetrotide prescription and Mr. Fischer's Increlex prescription;

d. Directing the Secretary immediately to ensure that the Medicare Part D program covers Mrs. Layzer's Cetrotide prescription and Mr. Fischer's Increlex prescription;

e. Awarding to Mrs. Layzer and Mr. Fischer reimbursement of their out-of-pocket expenses caused by the denials of Part D coverage, together with interest thereon;

f. Awarding Mrs. Layzer and Mr. Fischer their costs and expenses incurred or advanced in this action, as well as reasonable attorneys' fees; and

g. Granting Mrs. Layzer and Mr. Fischer such other and further relief as this Court may deem just and proper.

Dated: New York, New York
December 17, 2007

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